IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Klinman et al.

FILED VIA EFS
December 13, 2011

Application No. 10/666,022

Filed: September 17, 2003

Confirmation No. 7954

For: METHOD OF TREATING AND

PREVENTING INFECTIONS IN

IMMUNOCOMPROMISED SUBJECTS WITH IMMUNOSTIMULATORY CPG

OLIGONUCLEOTIDES

Examiner: Michelle S. Horning

Art Unit: 1648

Attorney Reference No. 4239-66899-01

SUBMITTED VIA THE ELECTRONIC FILING SYSTEM (EFS) COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 C.F.R.§ 1.132

We, Dennis M. Klinman and Daniela Verthelyi declare:

- 1. We are the co-inventors of the above-referenced patent application.
- 2. We are also co-inventors of the U.S. Patent No. 6,977,245 (Klinman et al.) with Ken Ishii, James J. Mond, and Mayda Gursel. Klinman et al. was published after the filing date of the present application. U.S. Published Patent Application No. 2003/0060440A1 is the first U.S. patent publication corresponding to Klinman et al. U.S. Published Patent Application No. 2003/0060440A1 was published on March 27, 2003, which is also after the filing date of the present application.
- 3. Ken Ishii, James J. Mond, and Mayda Gursel contributed to the invention claimed in U.S. Patent No. 6,977,245, specifically they contributed to the specific substantially pure or isolated oligodeoxynucleotides (ODNs) as claimed in claims 1-13 of that issued patent. However, Ken Ishii, James J. Mond and Mayda Gursel did not contribute to the conception or

reduction to practice of any methods for inducing an immune response to *Leishmania* that are disclosed in Klinman et al.

- 4. All of disclosure in Klinman et al. that is directed to a method of increasing an immune response to *Leishmania* in a subject by administering a therapeutically effective amount of an immunostimulatory ODN is the sole work of Dennis M. Klinman and Daniela Verthelyi. As one specific non-limiting example, the experimental studies disclosed in example 9 are the sole work of Dennis M. Klinman and Daniela Verthelyi.
- 5. Klinman et al. discloses the specific nucleotide sequences for D19 (SEQ ID NO: 176), D35 (SEQ ID NO: 177), and D29 (SEQ ID NO: 178). These ODN sequences are also the sole work of Dennis M. Klinman and Daniela Verthelyi. Ken Ishii, James J. Mond and Mayda Grusel did not contribute to the conception or reduction to practice of these specific ODNs.
- 6. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

By Demit 4	Date_	DEC	г,	2011	
Dennis M. Klinman					
Ву	Date				
Danielal Verthelvi					

SAS:sas 12/08/11 4239-66899-01 Declaration Under 37 CFR 1 132.doc E-153-2002/0-US-03Attorney Reference Number 4239-66899-01
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By	Date	
Dennis M. Klinman		
By (Auri)	Date_ 12~ 8~ 11	
Danielal Verthelyi'/ \(\)		